ADDI ALTERAM PARTEM

ISSN 1710-9477

Legislative Assembly of Ontario

Second Session, 40th Parliament

Official Report of Debates (Hansard)

Monday 22 April 2013

Standing Committee on Social Policy

Oversight of pharmaceutical companies

Assemblée législative de l'Ontario

Deuxième session, 40^e législature

Journal des débats (Hansard)

Lundi 22 avril 2013

Comité permanent de la politique sociale

La surveillance, le contrôle et la réglementation des entreprises pharmaceutiques

Chair: Ernie Hardeman Clerk: William Short Président : Ernie Hardeman Greffier : William Short

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Hansard Reporting and Interpretation Services Room 500, West Wing, Legislative Building 111 Wellesley Street West, Queen's Park Toronto ON M7A 1A2 Telephone 416-325-7400; fax 416-325-7430 Published by the Legislative Assembly of Ontario





Service du Journal des débats et d'interprétation Salle 500, aile ouest, Édifice du Parlement 111, rue Wellesley ouest, Queen's Park Toronto ON M7A 1A2 Téléphone, 416-325-7400; télécopieur, 416-325-7430 Publié par l'Assemblée législative de l'Ontario LEGISLATIVE ASSEMBLY OF ONTARIO

ASSEMBLÉE LÉGISLATIVE DE L'ONTARIO

STANDING COMMITTEE ON SOCIAL POLICY

Monday 22 April 2013

COMITÉ PERMANENT DE LA POLITIQUE SOCIALE

Lundi 22 avril 2013

The committee met at 1401 in committee room 1.

OVERSIGHT OF PHARMACEUTICAL COMPANIES

WINDSOR REGIONAL HOSPITAL/HÔTEL-DIEU GRACE HOSPITAL

The Chair (Mr. Ernie Hardeman): We'll call the Standing Committee on Social Policy to order. We are meeting this afternoon to hear deputations on a study relating to the oversight, monitoring and regulation of non-accredited pharmaceutical companies.

Our first deputation this afternoon is from the Windsor Regional Hospital/Hôtel-Dieu Grace Hospital. Each one can introduce yourself as you speak. We hope you do that. Introduce everyone, and everybody gets a turn to speak. That way, Hansard will have everybody's name—not only that, but they'll have it properly in the record rather than depending on my pronunciation.

With that, we also ask you all to go through the swearing of the oath, so I'll turn it over to the Clerk to do that.

The Clerk of the Committee (Mr. William Short): All right. I'll just go right to left. Dr. Ing?

Dr. Gary Ing: Yes.

The Clerk of the Committee (Mr. William Short): Do you have the Bible in front of you, or did you want to do the affirmation?

Dr. Gary Ing: I'll do the affirmation.

The Clerk of the Committee (Mr. William Short): Okay, so you can just raise your right hand, please. Dr. Ing, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Dr. Gary Ing: Yes, I do.

The Clerk of the Committee (Mr. William Short): Thank you. Mr. Schneider?

Dr. Kenneth Schneider: Dr. Schneider.

The Clerk of the Committee (Mr. William Short): Right; yes. Did you want to swear the oath or be affirmed?

Dr. Kenneth Schneider: Be affirmed.

The Clerk of the Committee (Mr. William Short): Can you just raise your right hand, please? Dr. Schneider, do you solemnly affirm that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth?

Dr. Kenneth Schneider: Yes, I do.

The Clerk of the Committee (Mr. William Short): Thank you. Christine Donaldson: Did you want to swear the oath or be affirmed?

Ms. Christine Donaldson: I'll swear the oath.

The Clerk of the Committee (Mr. William Short): Okay. You have the Bible? Thank you. Ms. Donaldson, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Ms. Christine Donaldson: I do.

The Clerk of the Committee (Mr. William Short): Thank you. Mr.—can you pronounce the last name?

Mr. David Musyj: MOO-shay.

The Clerk of the Committee (Mr. William Short): Do you want to do the oath as well? That's fine?

Mr. David Musyj: Sure. Yes, please; thank you.

The Clerk of the Committee (Mr. William Short): Okay. Mr. Musyj, do you solemnly swear that the evidence you shall give to this committee touching the subject of the present inquiry shall be the truth, the whole truth and nothing but the truth, so help you God?

Mr. David Musyj: Yes.

The Clerk of the Committee (Mr. William Short): Thank you.

The Chair (Mr. Ernie Hardeman): Thank you all for that. At this point, we will advise you that you will have 20 minutes to make your presentation. Then we will turn it over to questions from the committee. This time, the questions will start with the third party. So—

Interjection.

The Chair (Mr. Ernie Hardeman): No, I think they had it first last time. My memory—you know, they don't come any better than that. But that's not the hearing; it's not about my memory.

With that, we'll turn it over to the panel.

Mr. David Musyj: Thank you, Mr. Chair. I'm going o start.

Thank you, committee members. My name is David Musyj. I'm president and CEO of Windsor Regional Hospital. I'm proud to say that I work with the most caring and compassionate team members at Windsor Regional Hospital. Today with me are three members of that team. Starting from my left is Ms. Christine Donald-

son, who's our regional director of pharmacy. Next, to her left, is Dr. Ken Schneider, our chief of oncology. Furthest from me is Dr. Gary Ing, our chief of staff.

Why are we here today? It's to provide answers to this committee, and also for us to get answers on how this possible medical error could have happen, to learn from it and to ensure it never happens again. We are all here to help get answers for the 290 patients and families that we harmed. Our patients who provide their trust in us and the system we work in deserve nothing less. It is their system. We all get paid by them, every single one of us in the room. We report to them.

There is a concept at Windsor Regional Hospital we hold near and dear to our hearts in everyday care. It is called "just culture." You might ask, what is just culture? Implementation of a just culture provides the cultivation of mutual trust whereby individuals are encouraged for executing safe acts or for submitting necessary information regarding safety. Organizations seeking to establish or maintain a just culture must realize that weaknesses need to be exposed and examined if systems are to be effective in enhancing safety. Just culture is also developing a preoccupation with failure or, in other words, becoming an expert at looking for trouble and doing something about it. Effective organizations treat all failures or near misses as windows on the health of the system and never stop fixing them.

What just culture is not: It is not blame and shame, so please, as you proceed down the road you are taking, do not blame and shame. Otherwise, if you do, look in the mirror first. We all wear this one. The only ones that do not are our bosses: the patients and families who we harmed and those we care for on a daily basis.

With respect to our approach to responding to this sentinel event, the three individuals who are here with me today formed a part of our response team that addressed this issue under the terms of our hospital's "Management of a Sentinel Event" policy.

I now will hand the podium over to Christine, Ken and Gary to introduce themselves in more detail.

Ms. Christine Donaldson: I am Christine Donaldson and I am the regional director of pharmacy services for Windsor Regional Hospital and Hôtel-Dieu Grace Hospital. I am a registered pharmacist in Ontario and have practiced for most of my career in hospital, the past 15 years in the Windsor community. I also hold a master's degree in education and was on faculty just up the street here at the University of Toronto, and remain an adjunct professor at Wayne State University over in Detroit, Michigan.

I became director of pharmacy at Hôtel-Dieu Grace first, in 2001, and then became a regional director of both Windsor hospitals in 2005. My key responsibilities are to advance pharmacy clinical programs, to lead safe medication practice and to insure a coordinated distribution system for all medications.

One of my current professional roles includes serving as a council member of the Ontario College of Pharmacists. The Ontario College of Pharmacists regulates pharmacy to ensure that the public receives quality services and care. OCP council is comprised of 15 pharmacists, two of whom must represent hospital pharmacists, elected from the electoral districts of the province; two pharmacy technicians; between nine and 16 public members appointed by the Lieutenant Governor in Council; and two of the deans of the faculty of pharmacy.

Since November 2005, I also represent both Windsor hospitals as a voting member on the Medbuy pharmacy committee, which is part of the structure of this group purchasing organization. This role includes giving professional input to Medbuy's strategic team with respect to their contracting decisions and the request-for-proposal process.

I first became aware of this incident involving the chemotherapy drugs on the afternoon of March 27, after a pharmacy manager at London Health Sciences Centre called to alert us at approximately 4 p.m. All product within Windsor Regional Cancer Centre was immediately quarantined. After being notified, the fluid from one sample IV bag was extracted and it was verified that extra fluid was present in the bag beyond the labeled volume. With this result, I directed the pharmacy staff to begin preparing all cyclophosphamide doses in-house and patient-specific. This practice continues to today.

Immediately after London Health Sciences Centre staff notified us of the issue, we were contacted by Marchese staff doing the same.

In accordance with our internal policies and procedures, I notified the relevant vice-presidents and president and CEO later that afternoon, and we started to immediately investigate the extent of this drug error with respect to our patients.

On March 28, we started to meet as a clinical team to discuss the information we had received up to that point, continued to receive and continue to determine as a result of our internal investigation. On Thursday, March 28, our sentinel event management policy was in full implementation, with our CEO taking responsibility for incident lead, and a detailed plan was put into place with respect to notification of patients and families. The goal was to start notifying patients on Monday, April 1.

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This plan included verifying the names, addresses and phone numbers of impacted patients; creating a letter to be delivered to all impacted patients within 24 hours; creating a call-in centre for patients and families to call in after receipt of the letter and a call-out centre for all patients and families to be personally called even though they received the letter; appointment schedules prepared for patients and families to meet with their individual oncologists over a week-to-10-day period; and scheduling of town halls for families and patients to attend in group sessions.

Over the Easter weekend, we validated our patient treatment list, prepared our patient letter, created the callin centre to ensure appointments could be booked simultaneously and seamlessly, and trained staff who were calling patients on the process and to expect a range of emotions and how to try to address them.

While all patients were being notified, I also participated in three patient-family forums that were held to share our knowledge of the chemotherapy incident and to provide our commitment to learn from this event and to prevent future errors from occurring.

I would like to express personally my deep regret for the significant anxiety that this incident has caused for our cancer patients and for patients overall. I pledge to help to enhance the hospital medication system to make it safer and stronger for all patients so this never happens again.

Dr. Gary Ing: Good afternoon, everybody. My name is Gary Ing. I've been a family physician for the last 35 years in Windsor; I have been the chief of staff at the Windsor Regional Hospital for the past 18. I have many responsibilities, one of which is to collaborate with representatives of other disciplines to create an environment that promotes commitment to continuous improvement of patient care.

The changes in our health care system during the past 10 to 15 years were dramatic and unpredictable. I am sure that, as members of this distinguished committee, you are all well aware of the many challenges and constraints facing us currently.

As Canadians, we all take pride in having one of the best health care systems in the world. When an incident like this occurs, we need to refocus and critique ourselves on our processes. We have to identify any existing gaps and correct them immediately.

On March 27, 2013, we were made aware of the situation with cyclophosphamide. Windsor Regional Hospital took immediate action, with the patients and families being our focus. The next day, as you have heard, Mr. Musyj implemented our sentinel event policy. A team was assembled to develop a plan to address this issue. Over the Easter weekend, our team came up with an action plan. The primary focus was to disclose this matter to our 290 patients and their families as quickly as possible. We also had strategies in place to meet with patients and families to discuss their concerns. Within a week, all patients and families were contacted.

Going through this process, it is quite obvious that everyone has been adversely affected emotionally: the patients, their families, and our hospital staff. It also made us realize that our health care system is vulnerable to deficiencies of this nature. No matter what challenges lie ahead, we have the responsibility to advocate for our patients' safety and well-being. We intend to learn as much as we can from the findings of this incident and apply strategies to mitigate any potential risk in our other programs. Our patients deserve the best, and Windsor Regional Hospital is fully committed to outstanding care. Ken?

Dr. Kenneth Schneider: Thanks, Gary. Good afternoon, everyone. I do thank you for this opportunity for us to share our insight into this recent event. My name is Ken Schneider. I'm chief of the department of oncology

at Windsor Regional Hospital and physician lead in radiation therapy for the Erie St. Clair Regional Cancer Program. I've served in the role as chief for 12 years now.

I was born and raised in Windsor, and I was fortunate enough to return to my home community to deliver care to residents of Windsor and surrounding areas.

Besides my administrative responsibilities, I practise in a spectrum of disease site disciplines within oncology, including breast cancer, lymphoma and a number of other sites over the past 21 years. That's getting more and more painful to say, thinking back over 21 years of practice, but with each passing moment, there's one thing that really kind of resounds, and that's that I do this for patient care. That's what keeps me practising medicine.

I wanted to be a physician since I was eight years old. I parted ways with my appendix at that age, but became the proud owner of some old, dusty medical books from my surgeon; that's another story for another day.

A fundamental principle firmly embedded within the Hippocratic oath is the concept of "Do no harm." When scenarios such as this recent event occur, our initial instinct, as physicians, no matter what the root cause, is to ensure that further harm to patients is minimized, be it physical or emotional. Full and immediate disclosure of accurate information, an overriding principle of our institution's culture as a whole, followed by the steps as outlined by my colleagues, allowed the necessary management of our patients affected by this error. In addition, when an error occurs, it is critical to understand how it came about in order to learn from that experience and ensure that steps are taken to mitigate any future potential errors.

We must strive to minimize errors in the care of patients because we are privileged to have studied and worked very hard for this unique opportunity to serve them. For this reason, they place their trust not only in us but in the system. The professionalism, dedication and expertise of our hospital pharmacy program and staff are second to none. The precision to which their work benefits our patients is a daily standard. They will use this experience to gain even greater insight into the checks and balances to ensure patient safety.

As physicians, we respect that medicine is a complex blend of art and science, and of clinical judgment and evidence-based practice. The art component of medicine is the ability to use science with the evidence base that supports it while respecting the many unknowns that remain when studying the human condition and, hopefully, thus providing best care. This recent event requires us, as physicians, to counsel and guide our patients with our knowledge to the best of our abilities.

There's no data that allows us to confidently isolate this single factor of a variable dose reduction as to any deleterious effect it may have on our patient's outcome. However, based on (1) the many variables that remain unknown in cancer biology and therapeutics, and (2) the fact that a specific dose of a chemotherapy drug is prescribed based on clinical studies of that specific dose,

but not because one dose is the absolute required or only dose that will be effective, would indicate that the probability of a poorer outcome is very small. However, an absolute reassurance to our patients would be impossible, and we must acknowledge this. In addition, the emotional aspect of living with a potential risk of cancer progression or recurrence, no matter what the underlying reason, cannot be underestimated.

Ultimately, our role to these patients is to place this error into proper clinical perspective, respecting their concerns but encouraging them that, as physicians and as a respected health care institution, we will continue to advocate for best care always.

The Chair (Mr. Ernie Hardeman): Thank you all very much for your presentation. With that, we will start with the questioning and Ms. Gélinas.

M^{me} **France Gélinas:** Thank you so much. My first series of questions—first of all, thank you all for coming. I can guarantee you that we share the same goal that you do. I don't want harm to happen to anybody who has already had a tough time.

I realize that sometimes just talking about it, for some people it helps, for other people it brings more hardship, and I would say I'm sorry about this. The aim is not to harm them again. It's really for us to do the same thing you did, Mr. Musyj. You said in your opening statement that you want to learn so that it doesn't happen again. I want to assure you that this is what we're trying to do.

My first comment is to you, Ms. Donaldson. I was impressed by your resumé. You seem to be very active in the field. On your college also, I know that this is voluntary work that eats up a lot of a person's time. I take it that you know full well what the college does, that the college has oversight of their members, of pharmacies, etc. Did you know that this branch of Marchese was not regulated?

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Ms. Christine Donaldson: Yes, thank you. First off, I would like to echo as well the mandate of the Ontario College of Pharmacists, which is really one of public protection. All of the activities under the Ontario College of Pharmacists are to do that, to ensure the safety of the public members.

In the correspondence and the information we received through this process, there was some information shared with us regarding Marchese pharmacy that dealt with some issues around their accreditation status. We're still understanding that more fully, but it would be accurate to say that the information upon which we based some of our decisions was through the understanding of how they were regulated.

M^{me} **France Gélinas:** Just so that I'm clear, if we rewind to before March 27, before the first phone call and the series of events that is now well known to all, you had had a relationship with that supplier for how long?

Ms. Christine Donaldson: It was dating back to February 2012.

M^{me} France Gélinas: So for a full year you had had a relationship with them. I take it you've had relationships with other pharmacies and other members of the College of Pharmacists. Was there anything that would have led you to believe, from February 2012 and before March 27, that this grey area existed?

Ms. Christine Donaldson: At that time, we were under the impression that there had been some safeguards put in place. I think as the investigation unfolds, we'll continue to find out more about that, as far as what was the actual system process, or the system behind it, as far as regulation of compounding pharmacies. As you've seen in some of the dialogue between the regulatory bodies and our college, there was definitely some discussion, as we've said, before and after the event that has come to light.

M^{me} France Gélinas: So it's fair to say that when you entered into discussion with Marchese pharmacy, you basically went with good faith that the service they were going to provide to you was going to be provided by a body that had oversight?

Ms. Christine Donaldson: I think it's safe to say that, ves.

M^{me} France Gélinas: You took it for granted that the oversight was there because it's there everywhere else.

Ms. Christine Donaldson: Yes.

M^{me} **France Gélinas:** I won't put words in your mouth, but that's how you went.

If we look at prices—I don't know if you can tell me, but you're now doing the work in-house. If we compare this to the price of having it being done elsewhere, is it cheaper doing it the way you're doing it now, or was it cheaper when you had it done at Marchese?

Ms. Christine Donaldson: I think to answer that question I would just stress that the reason for us purchasing compounded medication in the first place was not based on price necessarily; it was actually around a safety risk that we had documented or had become aware of in terms of our own practice. It's the specifics of how this medication is actually prepared. It's very complex. As you know, in a chemotherapy preparation there's a series of very important steps that you need to take to ensure not only the safety of the product for patients, but as well for protecting the staff and the workers who handle the medication. In that case, really, cost didn't come into it as a factor. It was more safety and risk that had actually motivated us to choose this product from Marchese or another outside buyer.

M^{me} France Gélinas: Okay. Was there a series of events that led you to the point where you thought, on a risk-benefit analysis, the risk of doing it in-house—was there an escalation of risk? Because you have been providing chemotherapy treatment for a long time in Windsor.

Ms. Christine Donaldson: Yes, and again, we do provide the majority of our medication, chemotherapy medication included—it is prepared in-house. So this is one of only three items that we were actually having supplied to us by Marchese. Previous to that, we had been

using another supplier of this cyclophosphamide chemotherapy product. So there wasn't necessarily a series of steps or an escalation of steps, as you suggested. It was really part of our internal quality management system, I suppose, where it was addressed. Staff brought it forward; we made the decision to use an alternate product. And again, that is best-practice driven. Again, there are a number of standards that would support that type of procurement.

M^{me} France Gélinas: Are you comfortable now with having it done in-house? The risk of compounding those drugs has not changed significantly. There hasn't been any scientific breakthrough to make them safer to handle. Are you comfortable having them mixed in-house now?

Ms. Christine Donaldson: Just to reiterate, the majority of our chemotherapies are prepared in-house by our own staff, so this was just really one item that we weren't preparing, per se, in our own facility. It had just been added to our current structure. Our staff are already well trained, well versed, in preparing chemotherapy, and we have our own internal quality checks that, as you can imagine, continue to be our practice. Again, we'll be self-evaluating that practice as a result of this incident.

M^{me} France Gélinas: I'm trying to get a picture in my mind. You had identified some safety concerns—enough to decide to look at outside procurement. When this happened, you brought it in-house and everybody was comfortable with it? What's the difference between then and now?

Ms. Christine Donaldson: We need to be more clear regarding the specific chemotherapy preparation. It is actually procured as a vial of powder. Added volume has to be added to it by our staff. It then is a little bit more difficult to dissolve. It becomes a solution, and then it gets injected into the final IV solution. So it's really those stages and those steps that were adding a little bit of the complexity of the time, and that had led us to procure this other pre-mixed product.

M^{me} France Gélinas: Go ahead.

Mr. David Musyj: Just to help out, the decision, as a result of this event, was to start making the particular product in-house. That decision will continue to be reevaluated on an ongoing basis. I've discussed this with Christine, with other members of the hospital team: "As a result of this, how do we move forward?" It was with those discussions that we said, "For now, we're going to prepare it in-house and put the various safety mechanisms in place." As a result of all of these issues that are now coming to the surface, the decision of using another outsourced company to do this is not the decision we're making right now until it is settled about what is going on with respect to the accreditation, non-accreditation and oversight of these particular companies.

It's almost a day-to-day decision in the sense of a discussion with respect to, "Are we comfortable?" We made a decision in the first place to go outside, as you point out. As a result of this incident, we're now doing it inside. What has changed? Do we still have a concern? Through discussions with Christine and the team, no,

they are comfortable now with respect to this—far more comfortable than going immediately to another outside agency to do this—and have put into place the necessary safety restrictions for the benefit of the staff and, of course, our patients in preparing this drug on a perpatient basis internally. We've been doing that ever since March 27 and will continue to do that until there is some clarity with respect to the landscape that is going on, and some very clear focus with respect to the industry and oversight.

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M^{me} **France Gélinas:** Okay. Ms. Donaldson, you mentioned that before you dealt with Marchese, you also dealt with an outside procurement. Who was it?

Ms. Christine Donaldson: At this point, we had partnered, through a previous contract, with another CIVA—central intravenous admixture, sorry; I'm using an acronym here—service provided by Baxter Corp.

M^{me} **France Gélinas:** By Baxter? Okay. And how long had you had this procurement with Baxter?

Ms. Christine Donaldson: The cyclophosamide product: It had been since July 2011.

M^{me} France Gélinas: Okay. And what made you change from Baxter to Marchese?

Ms. Christine Donaldson: There was a contracting decision—an award through our Medbuy organization that had prompted the change.

M^{me} France Gélinas: So Medbuy went for an RFP? Okay. And I take it that Marchese was the happy winner—

Ms. Christine Donaldson: That's right.

M^{me} France Gélinas: —of this procurement. Okay.

I'd like to come back a little bit. In your answer, you make it clear that you want to make sure that there will be accountability. You're willing to take the risk of mixing those drugs in-house and will make future decisions once the accountability issue is settled. Had it ever occurred to you that the accountability could rest anywhere but with the Ministry of Health? Did you ever think that it was your responsibility to do that oversight, that it was a hospital responsibility to check on oversight?

Ms. Christine Donaldson: I'd defer that to David to answer.

M^{me} France Gélinas: You get the tough questions.

Mr. David Musyj: Sure. With respect to that answer, it could possibly be. We're part of the problem here. As I stated in my opening statement, now is not the time to point fingers; it's the time to learn about how this happened. So we're participating in a review that's being conducted by Dr. Thiessen, and we look forward to his comments. We met with him last week as a team, and we look forward to hearing from him with respect to what he finds.

Where does the responsibility lie? What changes can we make as a hospital and as hospitals, because it's a system issue, that could avoid this happening in the future with respect to this drug—or any other drug, for that matter? At the end of the day—I can tell you, when

we met in our town halls with the patients and families—yes, when we got the IV bags, could we have weighed them? Sure. Could we have pulled every 10th or 20th bag, extracted saline out of it and measured every bag ourselves? Sure. We talked about that openly with our patients and families.

Is that reasonable? This is one of, to my understanding, some 2,000 different types of drugs that we dispense out of the hospital on a daily basis. Is that reasonable? Should the oversight happen at the source? Should it happen at the hospital? Should it happen at both places? That's what we need to learn. Those are the answers we need to get. Those are the reflections we've had internally. Now we need to have them as a system and, as a part of this review, learn from it, and figure it out so that this never happens again to this particular drug—or any other drug, for that matter.

M^{me} **France Gélinas:** You've mentioned that you've already started to meet with Dr. Thiessen, who will be doing the review. Who will be invited to talk to him, or who will he talk to at your hospital?

Mr. David Musyj: He talked to our whole incident team. He was given wide-open access to talk to anybody whom he wished to talk to at the hospital. He met with a broad selection of individuals; all of us here at the table he met with, and our full sentinel event team, which contains nurses. Then he went to the actual area in which the drug was brought into the hospital, and also dispensed to patients and provided to patients. He was able to talk to anybody and everybody he wanted to, and he's more than welcome to return if he needs to have follow-up.

M^{me} **France Gélinas:** If he reaches out, you make them available. Is it true in reverse? As in, if somebody from your hospital wanted to talk to him, how would that go?

Mr. David Musyj: They can contact him directly if they wish to, but they have a opportunity to do so. At any point, if anyone wants to talk about this to anybody, I would ask them to reach out to him. There is no restrictions on his availability to talk to anybody or hear from anybody.

M^{me} **France Gélinas:** Would you say that the same thing applies to this committee, if we wanted to talk to some of your staff?

Mr. David Musyj: Yes. I wouldn't want you to be calling them in the sense of—but if they want to talk to you, if you call them directly and they wish to talk to you, more than welcome. As long as there is no breach of patient confidentiality, I have no issue with respect to that. So if you want to talk to people—I'm not going to give you their home phone numbers. You can have mine if you want.

M^{me} France Gélinas: No.

Mr. David Musyj: Yes, more than welcome. Anyone is welcome to discuss this issue with the staff. What we tried to do, though, for our staff—because our staff will be asked by patients and families about this particular issue—we've said to staff, "Please direct them to this phone number." We had a call-in number for patients and

families to call in. So we make sure we are talking to the patients' families, in the sense of giving them the information.

The last thing—and I use this as an example—is for a patient or a family to see me out in the community, ask me a question and assume the answer I'm giving them with respect to this event resolves it for them. We wanted to make sure, "No, you need to talk to this call-in centre, because the person you need to talk to to get your answers is your oncologist," be it a patient or a family member. "That's who you need to talk to, not David Musyj, president and CEO. I can provide you as many answers as I can, but you really need, on an individual basis"—so that's where we try to direct everybody. Successfully, we've been able to do that. A patient or a family member who wants to talk to their oncologist about this has had the opportunity to do so.

The Chair (Mr. Ernie Hardeman): You have two minutes.

M^{me} France Gélinas: I'm going to keep my two minutes.

The Chair (Mr. Ernie Hardeman): Okay. Ms. Jaczek.

incident appropriate?

Ms. Helena Jaczek: First of all, I'd like to echo some of the comments made by my colleague Ms. Gélinas in terms of what we're trying to achieve here, which is clearly to learn from this experience, and, from the government's perspective, are some of the measures that we've put in place since we heard about this particular

Just to start off, as a physician, I feel very much, as the physicians in the room, and I believe all of us, that this is something that from the patient perspective is clearly a scary situation. Dr. Schneider, you made the comment that even though the probability of poorer outcome is very small, absolute reassurance to our patients would be impossible, and we must acknowledge this. The whole emotional context here is very important, so I was very pleased to hear about the town hall that you held there to talk to patients and families.

From a clinical perspective, and perhaps to Dr. Schneider: Over the last year, since this product was in use, had you noticed any changes in terms of predictable patterns of cancer progression or regression? Was there anything unusual that you had been following?

Dr. Kenneth Schneider: That's a good question. In terms of the population that's treated with this particular drug, the two main populations are breast cancer in the adjuvant setting where cancer has been removed; cyclophosphamide is one of a combination of drugs given to minimize the risk of recurrence. The other proportion of patients is non-Hodgkin's lymphomas, where you're giving the drug for a measurable disease that's still present. In neither of those groups was there anything from my physician group that they indicated after hearing of this, "Gee, that's interesting. I could relate that to a difference in clinical outcome." There's nothing that would substantiate that, and it's likely because, in the breast population, there's no disease to measure. It's

given on a preventive basis. There were no uncommon, unusual increased relapses within that period of time. In the lymphoma population, it's one of a combination of effective drugs where the response rates are actually very good. Nothing really fell out in terms of identifying a clinical change.

Mr. David Musyj: Just to follow up, because I think it's timely: one of the things we learned from the town hall that came up—because what's amazing is, patients and families, as you know, stricken by cancer, as everyone knows, have insight that, to this day, I marvel at. To a person, in each of the independent town halls, they were very similar, and one of the issues they brought up: "Could we be used as a test group moving forward? Could we talk and have the approximately 1,200 individuals be monitored to determine if there is any measurable outcome?" That was one thing that came up, and I think there's actually work under way outside of this to have a review. Because unfortunately, from the literature—and correct me if I'm wrong Dr. Ing or Dr. Schneider-there is very little literature out there about the impact, negatively, as a result of underdosing at this level. So your point's well taken.

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Ms. Helena Jaczek: Thank you, that's very helpful.

Now to Ms. Donaldson: Just so I fully understand, since February 2012, Marchese Solutions delivered to the hospital IV bags with what was assumed to be the appropriate dose. We've heard that there was something like a 20% reduction in the dosage, so that the dilution had, obviously, been increased. This isn't to point fingers. I'm sort of surprised that a 20% increase in saline wouldn't have been fairly noticeable. Can you just lead me through that?

Ms. Christine Donaldson: Absolutely. It's a good question. Again, we did a bit of a show and tell with our patient family forums and brought them an example IV bag just to explain the process, because it's a well-known industry standard; I'll call it that. A pre-filled IV solution bag would have more than the stated volume. So in other words, we're talking about an IV solution bag that had 250 millilitres from the manufacturer. In this case, it was Hospira. That was the known overfill. So the known stated volume was 250 millilitres; however, it's a known industry standard that there's 20 to 30 millilitres higher than the 250 in each bag. If you actually hold them up side by side—it depends on how much air is within the IV bag, it depends how it's been manipulated, it depends how long it's been out of the overwrap packaging—the real difference, even to the naked eye, would be highly difficult to distinguish. I think that's an important point to bring out. It's a clear-colour solution. The staff handling or looking at the drug-or the labeled amount that was there—it would be very difficult for them to distinguish that 20% difference.

Ms. Helena Jaczek: Thank you. Then nothing was done within the hospital to further dilute—you didn't touch it; it was literally, "This is the IV bag. This is what got hung."

Ms. Christine Donaldson: Right. I'll just explain that a little bit further. The oncologist would actually prescribe a dose, to the milligram, because it's important in cancer chemotherapy that it's very much determined by the patient's weight and other status. The dose would be drawn up, the number of millilitres that would result from that dose from the bag of saline solution with the chemotherapy in it, and then that amount, that specific volume for the patient, was then injected into a small mini-bag that was then delivered to the patient. There was no further dilution; however, it was actually injected into the mini-bag and then the entire amount of that second mini-bag was actually administered to that specific patient, as per their oncologist's order.

Ms. Helena Jaczek: Okay, thank you.

Now I understand that the actions that you took—we had them detailed to us by Michael Sherar last week. Windsor was—I was impressed by a rapid response in terms of the actions that you took. Can you talk to us a little bit about your communication with the Ministry of Health and Long-Term Care? When did that occur and how has that conversation continued?

Mr. David Musyj: I can speak to that. Back when we found out about this as an organization—late Wednesday, later in the afternoon, into the Thursday—I recall specifically, as part of our policy, reaching out to the Erie St. Clair LHIN and informing them of this particular incident. You have to remember that at that moment, late Wednesday into Thursday, it was trying to pull this information together with respect of what actually occurred, how many patients did it possibly impact. So it was a lot of information gathering, trying to get as much information as possible. So notifying the Erie St. Clair LHIN and ensuring that, either through CCO—Cancer Care Ontario-or through our Erie St. Clair LHIN, the Ministry of Health became aware of it immediately over the Easter weekend as well, or at least that, "There is an issue; we're investigating it and trying to get as much information as possible." That would have happened, at least from our point of view-I know that some other hospitals were aware of this issue in advance of us, so we were, from my information, last to know about this particular issue until London Health Sciences Centre called us at approximately 4 p.m. on the Wednesday. Does that answer your question?

Ms. Helena Jaczek: Yes. Since then, what sort of communication have you had with the ministry or the LHIN or Dr. Thiessen or the working group or—

Mr. David Musyj: Ongoing and non-stop. With respect to our internal sentinel event management team, we started meeting that Thursday, and we met every day officially, had minutes of those meetings, and had discussions with respect to exactly what needed to be done in order to focus on the patients and the families and get notification as accurately and as timely as possible in as sensitive a manner as possible. In addition, ongoing communication: keeping the Erie St. Clair LHIN up to date as well as the Ministry of Health. As president and CEO, I'm on a working committee that has a phone call

daily with the Ministry of Health and the other hospitals involved regarding this particular issue and talking about broader system issues and moving forward. For instance, with the draft regulation, being notified that it's coming out, with the attestation document, and trying to move forward. It has been non-stop communication with the Ministry of Health and the Erie St. Clair LHIN.

Ms. Helena Jaczek: Since you've touched on the draft regulation, could you perhaps describe this for the committee and tell us what kind of impact it's going to have on patient safety?

Mr. David Musyj: Sure. We just got the draft regulation late Friday, and there is a 15-day period to get feedback. Christine has been asked to provide us some feedback. We'll be doing that and we'll be reaching out to the other hospitals and system players involved to find out what impact—because the last thing we want to do, of course, is to create a bigger problem trying to solve another problem. I appreciate the fact that there is this 15-day period for hospitals and other health care providers to provide comment; that there wasn't some unilateral implementation of a regulation that could create a bigger problem than the one we're trying to solve. That's what we're working through right now. But I can tell you, as a hospital system, in addition to this, our focus from day one, since March 27, has been focused on the patients and the families and our own staff in addressing this issue. We haven't, since Friday, had a considerable amount of time to look at the regulation and examine the impact of it.

Ms. Helena Jaczek: Ms. Donaldson, could you describe what's in the regulation?

Ms. Christine Donaldson: Sure. From my review, it does state that there would be some, I'll call them provisions, that would be more fully detailed as to how hospital pharmacies could procure medication, specifically IV-compounded medication, outside of its own facility. It does just basically lay out the provisions that would be necessary before that sort of arrangement could—

Ms. Helena Jaczek: With some sort of oversight of these facilities?

Ms. Christine Donaldson: Right. In different details, it does describe that there would need to be some sort of regulation or an accreditation status or some other type of, as you said, oversight to the supply chain.

Ms. Helena Jaczek: Could you please describe to us your ongoing quality assurance program with respect to pharmacy within-hospital?

Ms. Christine Donaldson: Thank you, and it was something I did want to note for this committee. Again, I'm very proud to be a member of the Windsor Regional Hospital staff. We have had a very strong quality-management system in place for a number of years. Many quality indicators are continuously monitored, and data is collected and action plans result. Specifically, medication incidents have been one of the top quality indicators for our entire institution. Again, this is public on our website. I encourage you to take a look at some of the success.

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As we outlined in our original statements, it's an ongoing, constant challenge to learn from the system and basically challenge each other on where the gaps are in the system. That way, we can continuously improve. For example, I am a co-lead of a working group. We meet weekly. We review all the med incidents that happen, or near-misses, which again is an opportunity to learn from a potential error before it actually reaches the patient, and we have discussions around what we could do to make the system stronger, including adding extra safeguards—extra safety measures and steps—within our own facility. That has been a long-standing practice.

Obviously, with this situation, we'll be continuing to do our own internal investigation into additional practices that we can put into place to ensure that we are, again, following those quality measures, including double-checks—you talked earlier about weighing the IV bags—anything that we can do to, again, ensure that the quality of our own product is of the best standards.

Ms. Helena Jaczek: Currently, when you talk about incidents, is this where perhaps the pharmacy sends a particular medication to a patient and the individual administering that substance or product notices that there is something that doesn't jibe?

Ms. Christine Donaldson: That's correct. It could be self-disclosing. Again, we have a very strong framework at our hospital, so we encourage reporting of incidents so we can learn from the system. It may be as simple as omitting a dose due to another patient care issue: A dose of another medication is omitted or given late. Again, we would encourage the nurse to submit that incident, put any of the reasons or the root causes behind why they believe that incident occurred, and then we start to discuss what we can do to strengthen the system around that individual nurse's practice or the pharmacy's practice.

As you said, it's very much a multi-disciplinary team approach. Again, as this incident shows, you're constantly challenging yourself to look for those gaps, because often you don't know they're there until you continuously look for them.

Ms. Helena Jaczek: And who do you report these incidents to?

Ms. Christine Donaldson: We have a vice-president who is also an active member of that team, and then all the quality indicators and action plans trickle up to our quality improvement plan for the entire hospital. So again, that's very much the flow of how that information goes forward.

Ms. Helena Jaczek: This is the quality-improvement plan pursuant to the performance agreement that you have with the ministry?

Mr. David Musyj: Yes. These medication errors are publicized hospital-wide. All front-line staff, our board quality committee—as Christine identified, our medication incidents are notified to the whole community on our website. But yes, it's tied back into the quality improvement plan pursuant to the Excellent Care for All Act. That's where the tie-in is.

Ms. Helena Jaczek: These do get reported to the LHIN and subsequently, presumably, to the ministry.

Mr. David Musyj: They are there for the world to see.

Ms. Helena Jaczek: Thank you. Now, Health Canada also has made some improvements, as we understand, mostly from the media, over the last few days. What are you aware of in terms of what Health Canada has done in relation to compounded drugs?

Ms. Christine Donaldson: At this point, we were asked to—I'll call it respond or indicate practices within our hospital sites that involve sterile IV compounding, including whether or not we had the facilities-human resources, proper practices—to continue or bring those practices in-house, similar to what we have done as a result of this incident. I also know that each facility will be asked, as David outlined, to complete an attestation form that would indicate how those quality assurance practices are in place to, again, ensure protection of the public; that that is a little bit more transparent, I guess I'll call it, to the public eye. Again, we've been asked to summarize our practices, and that is within hospital sites as well.

Ms. Helena Jaczek: Thank you. How much time do I have left?

The Chair (Mr. Ernie Hardeman): Two minutes.

Ms. Helena Jaczek: I'll keep my two minutes, as well, for the second round. Thank you.

The Chair (Mr. Ernie Hardeman): Thank you. With that, we'll go to Mr. Yurek.

Mr. Jeff Yurek: Thanks, everyone, for coming out. A long drive from Windsor—or a train, I guess; whichever was quickest.

Just a few questions, and then Christine will cut in here. Can you give me your view of Medbuy—how it operates, what it entails and the partnerships involved in it?

Ms. Christine Donaldson: Sure. I can start off by explaining my understanding. Medbuy is a group purchasing organization which Windsor Regional Hospital joined in 2005. It does a number of procurement actions, but specifically in the pharmacy realm. There is the strategy around Medbuy's—every single hospital that becomes a member of Medbuy has a senior executive on their board, and essentially Medbuy exists because of the member hospitals that represent those sites.

As a pharmacist leader, I was asked to participate on the Medbuy pharmacy committee—that's exactly what the name is—and it's essentially an advisory group. We meet monthly by teleconference and also twice a year face-to-face to discuss current issues. Everyone remembers too well the back order situation last year with our Sandoz supply, and as a result of those sorts of challenges, the team got together and created a list of 30 critical medications that must be a part of our strategy in terms of perhaps allowing dual awards to be given out to pharmaceutical companies, to prevent that sort of back order situation or shortages in the future.

We tend to have a very professional or advisory capacity at that level, really guiding some of the practices into the future for the pharmaceuticals that we would ask Medbuy to procure contracts for us.

Mr. Jeff Yurek: So at the end of the day, when you entered into an agreement with Baxter in 2011, and then Marchese, was that Medbuy or was it the hospital?

Ms. Christine Donaldson: Yes. There was a contract, as you said, in place and, again, part of the procurement guidelines is to—I kind of forget the name of it—issue a statement of single source?

Mr. David Musyj: Yes. Maybe I can help. What happened is that we, through Medbuy, had a contract, with all of the other hospitals, with Baxter. When that contract came up for renewal or expiry, from the information I have, there was notice that was posted. There was a thought, I guess, by Medbuy that Baxter was the only company that had the ability to continue the contract past the expiration, so they had to file a notice, which was publicly posted, wanting to sole-source, meaning wanting to continue with Baxter. The information I have is that Marchese at that point filed an objection to that sole-source. As a result, Medbuy had to go to the market at that time, went through a full procurement practice, and Marchese ended up being the successful proponent of the RFP.

Mr. Jeff Yurek: So Medbuy coordinates the procurement and the request-for-proposals?

Mr. David Musyj: They handle all of their procurement process. Now, as Christine outlined, she is one of the individuals in this particular contract that was involved in the procurement practice. Christine can talk about it; she can talk about how many people were on the procurement team. Everyone kind of has their own little slice of the RFP process that they evaluate and score, and then that goes back to Medbuy with respect to the eventual totalling and then seeing who was the successful proponent. If you want more detail, Christine can provide it

Mr. Jeff Yurek: Yes, if you can just do an overview of what you actually looked at when, say, comparing Baxter to Marchese or to any other product or company.

Ms. Christine Donaldson: Sure. As David outlined, I can only tell you my slice, right?

Mr. Jeff Yurek: Yes.

Ms. Christine Donaldson: Certain components were shared with the entire group and then, as you said, there were a number of individual—I don't know the total number. I would say it was between eight and 10 pharmacy committee members—so, again, directors of pharmacy similar to myself for the Medbuy hospitalsthat were given three or four elements of the criteria. We also helped to give the relative weighting of the criteria for the RFP, and I think that was an important step to involve the pharmacy committee members. As you can imagine, when you're being scrutinized for decisionsour committee has a very strong mission statement around quality over financial. If you look at the scoring criteria, "financial" is the smallest percentage overall, actually, in the weighting of the RFP. Other pharmaceutical criteria, business criteria and quality criteria were much more heavily weighted.

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I was essentially sent those three or four items off the RFP, asked to score them—there were actually three companies that came forward that met the initial cut-off for the RFP—and then we sent back our scoring to the Medbuy strategic team to then go ahead, collate, and continue to come up with the final award.

Mr. Jeff Yurek: Do you know if there was a prequalification for companies wanting to bid at Medbuy? Was there something set out in Medbuy that would prequalify them to allow them to go after contracts, which would check their references, check their ability to do the job, the previous history at performing that task?

Ms. Christine Donaldson: I believe that was part of the process. If you look at the RFP, those criteria had asked for some business criteria, producing any practice standards that they were meeting; those sorts of things. They were embedded almost in the—I don't know if I would call it pre-qualification, but I don't know if there were any more—for example, I know there were three bids that were assessed by our team, the pharmacy committee. I don't know if there were any more that were submitted and basically didn't meet the RFP language, but what was shared with us was that there were three successful companies interested in this business that had met the criteria, and we would continue to score them from that point on.

Mr. Jeff Yurek: But in that vetting process, though, the ability to see if Marchese was qualified or not—or oversight on this, OCP or Health Canada, if they were a compounder or a manufacturer. I know it's a really grey area out there, but—

Ms. Christine Donaldson: I know they were asked to submit, as part of the RFP, any standards, qualifications and certificates to show they were meeting any of the accepted practice standards. I believe that was embedded in the RFP process, but I wouldn't say it was, like I said, a pre-qualification.

Mr. Jeff Yurek: Thanks. Does the Ministry of Health deliver any guidelines to Medbuy or to the hospitals on procurement of medications? I wouldn't say equipment and such—that's a different category—but any guidelines for procurement standards that they should be achieving through the hospital's procurement of outsourcing?

Mr. David Musyj: Overall, just with respect to the broader public sector guidelines and directives with respect to procurement, they are rather detailed, not so much through the Ministry of Health but through the Ministry of Finance. We have very detailed directives with respect to what to procure, at what level do you have to start the procurement process and the whole details, and that covers not only drugs; that covers equipment; that covers paper; that covers pencils; that covers everything we purchase at the hospital.

Mr. Jeff Yurek: But nothing from the Ministry of Health that's saying, "If you're going to outsource this medical product, it has to have a certain standard that would be equal to or better than what you could produce in-house" or anything like that?

Ms. Christine Donaldson: I would answer that question by referring back to our initial comments around quality and safety. There are a number of standards that are out there that—the College of Pharmacists puts out standards; the Institute for Safe Medication Practices puts out standards. I think that is constantly part of the evolution of safety and practice. That would help inform our decision-making. There are guidelines published as well through the Canadian Society of Hospital Pharmacists. We would also follow their best practices. So I think it comes from many arenas in terms of indicating or directing our practice toward the best possible standards. There isn't one overarching guideline.

Mr. Jeff Yurek: Just two quick questions: Do you outsource any other compounded medications?

Ms. Christine Donaldson: No.

Mr. Jeff Yurek: And how are the bags coming from Marchese labelled?

Ms. Christine Donaldson: Sure. We did provide, actually, an example in our patient-family forums to help explain what we had experienced.

The label itself does list four grams of cyclophosphamide in 200 millilitres. That's how it informed us of the final concentration or stated concentration.

Mr. Jeff Yurek: The concentration wasn't on the bag, though?

Ms. Christine Donaldson: No, the concentration was not specifically listed on the bag. However, the total drug quantity in milligrams or, in this case, grams, and the total number of millilitres was stated.

Mr. Jeff Yurek: Christine, thank you.

The Chair (Mr. Ernie Hardeman): Jane?

Mrs. Jane McKenna: Thank you very much. My question is actually to Christine. Marchese maintains that its drugs were not defective, suggesting the problem was how the drugs were administered at the hospital, not how they were prepared. How do you react to that?

Ms. Christine Donaldson: Again, our concern is for our patients. That is paramount. The word "defective," I guess, has many definitions. Do I believe that there were the stated milligrams, the right drug, in that product, in that package? I do. We haven't done a qualitative analysis ourselves. I believe that there was a product produced according to what they believed the final concentration should be for our facility. Unfortunately, I think there was not that oversight, as you said, as far as the product produced and what the intended use was for our patients. I think that's where I'm challenged in terms of clinical practice and intended use of cyclophosphamide for cancer patients.

Again, I sort of take issue with that word "defective." Do I think it was prepared with the proper steps and the proper quality practices? Likely it was, and I guess the investigation will continue to help us delve into those issues, and hopefully we await Dr. Thiessen's report to share the outcomes so that we can improve the process from this point on.

Mrs. Jane McKenna: Thank you. My next question is this: I understand and applaud your commitment to

quality improvement, but what quality assurance processes are now in place, now that these drugs are outsourced?

Ms. Christine Donaldson: Thank you. Our current staff, again, are trained staff in product preparation, including for chemotherapy. In fact, all of our technicians are on the path to become regulated by the Ontario College of Pharmacists. The level of steps is probably between six to eight of product selection, a double-check to make sure that the right vial and the right IV bag are selected against a label that has already been reviewed by our pharmacist. Our pharmacist team actually produces—part of their internal quality checks is to double-check the prescription that is written by the oncologist; it's actually locked down. The label and the product cannot even be released until the pharmacist reviews it for accuracy and also for patient-specific lab results, etc.

At that point, then, as I said, one technician would procure the two items, the two products. A second technician would check that. Then the volumes would be withdrawn. Again, another set of eyes, another technician would be responsible for double-checking that process. Then it would be injected and it would be labeled appropriately, and then more checks. In almost every single one of those steps, staff have to initial and validate that they've taken those steps. Really, between the point when a physician actually writes a prescription to when it's actually handed over to the nurse to deliver, again, there's probably between eight to 10 safety checks that happen.

Mrs. Jane McKenna: Thank you very much. I just have one more question to Dr. Ing. Unpredictability makes any system vulnerable. I just wanted to know if you could elaborate on what you said in your opening remarks, that the last 10 to 15 years have been very dramatic and unpredictable.

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Dr. Gary Ing: My intent of that statement is this: We all know that we are under pressure in terms of the health care system, in terms of our resource allocation, demand by the population that we serve, and also the expectation that we have to provide the best care that we can in Ontario and also in Canada. So when you look at all these various factors, they are not necessarily on the same page. There are ups and downs and variability.

As a health care institution, we have to be responsible and we have to be creative and also make accommodations so that we can juggle the financial aspects, the demand, the quality of care, the efficiency. We've got to balance all those factors such that we can provide a service that we're supposed to to a community. That's why this is unpredictable, because this particular incident like this—how can we predict that to happen? A lot of things we carry out in practice. Standard practice is the way we practise, and the expectation is that when we receive a particular product or medication, we expect it to be the true, pure medication.

If I prescribe penicillin to my patients, when the pills come down from the pharmacy, we expect it to be penicillin. Unless there's some other appearance of a drug or something that would tip you off, you wouldn't know that. Then what you do is, you trace back to the processing like this, to the company and so forth. There are many, many generic companies out there for penicillin, for one thing. That's why it's very difficult when you don't have the awareness, and I think this particular incident really heightened the awareness for us. As you look at the various steps in the system, there are a lot of partners involved and a lot of people have to play a part, including the hospital ourselves here.

We certainly take full responsibility in terms of what we do, but we are also learning now from the investigators, from your committee and various sources as to how we can prepare ourselves to mitigate the risks in the system and to improve this. Even though it is a very tragic event, so to speak, we need to make something positive out of this. I do believe that if everyone is willing, we can make this a more positive story down the road

Mrs. Jane McKenna: Thank you.

The Chair (Mr. Ernie Hardeman): You have about two minutes left.

Mrs. Christine Elliott: All right. I'll try and make the most of it, then. I'd like to go back, if I could, to the original decision in 2011 to actually begin purchasing the prefilled solutions. I guess my question would be directed to Dr. Schneider and Ms. Donaldson. How did this decision come about? What precipitated it? Was there an incident or was this just something that came forward as best practices, and where did it come from? Was it physician-led, pharmacy-led, or how did it come about?

Ms. Christine Donaldson: It was pharmacy-led. As I tried to outline earlier, it was part of the practice—the safety. It came forward from staff, actually. Our own pharmacy staff came forward, in discussion with the current supplier, Baxter: Would this be an opportunity to have a compounded or a premixed solution as an opportunity to meet that quality practice? So it wasn't oncology-driven. There was no incident per se that prompted that. Again, it was more of a safety decision that had alerted us to the option.

Mrs. Christine Elliott: And what was the process for getting that approval? Was that discussed with the medical staff or was that just a decision that was made in pharmacy, and were medical staff aware of it?

Dr. Kenneth Schneider: As physicians, we're really the end-users. We're really not involved in the specifics of a process of how a particular drug is purchased, because of the fact that when you work in an environment where there's expertise at various levels and various programs, physicians don't weigh in on all those discussions.

Mrs. Christine Elliott: But this would have been a fairly significant change, would it not, and did it require any kind of approval in order to be able to proceed in this manner?

Ms. Christine Donaldson: I would just go back to indicate that the typical hospital practice for many years

has been—and again, this is not just within our site—to have compounded IV medications, whether it be antibiotics—and again, the list of products we're talking about here—cyclophosphamide was one of them, but there's an A-to-Z list of many items that are available in a premixed format. So again, that has been a relative norm—I guess I would call it a practice—to select some premixed products, again, with the rationale beyond actually getting the pure or the individual vials and compounding it in-house. That has been a long-standing practice.

Mrs. Christine Elliott: Thank you.

The Chair (Mr. Ernie Hardeman): Just a very quick comment: That concludes the time for the party, but—

Dr. Kenneth Schneider: Thanks very much.

The Chair (Mr. Ernie Hardeman): You wanted to make another comment?

Dr. Kenneth Schneider: I could maybe weigh in on where physicians do have a role, and that's more in the area of pharmacy and therapeutics, or MAC, where there's a therapeutic change in a dosing of a drug or there's a significant change in the indications for the use of a drug. That's where typically physicians would have input to make some decisions. That wasn't the case here.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes the time. Did you want your last two minutes, Ms. Gélinas?

M^{me} France Gélinas: Yes, please. I will be very brief. Either to Dr. Ing or Dr. Schneider, whoever wants to take the lead: I think, Dr. Schneider, you said it best. You work in an environment where there's expertise at many levels. Lots of what you rely on is made in the hospital, is an activity of the hospital, but lots of it is also for a partner in the community. I'm sure some of your patients go to labs in the community and have ultrasounds and X-rays and have all of this. But there is always that level of trust that when they go outside of your hospital walls, there is a level of oversight that is there so that the result you get back, whichever partner it comes from—the products that you get—was always—

Dr. Kenneth Schneider: You hope for it to be reliable

M^{me} France Gélinas: Yes, you hope for it to be reliable. Has this shaken your confidence in other parts of the system, that if a pharmacy—what we thought was a pharmacy, with the oversight of the college and everything else—can make a mistake like this—does that make you fearful of the rest of the partners in the health care system?

Dr. Kenneth Schneider: Gary, did you want to—

Dr. Gary Ing: Yes, if I may. I think a lesson like this—as painful as it is right now, we need to concentrate and focus on how we can do things differently. One is definitely to address this particular quality assurance practice of this particular area. But we need to take the same principles, same strategies, to look at the other areas, the other programs, in the hospital. We need to look at those. Those basic principles are going to be the same in terms of how we're going to manage a quality

practice program. You apply those principles to other programs.

You get your physician leaders and your administrators involved, because they're the ones who are close to the action. They can tell us if there are any flaws, any concerns about the processes we've put in place, and how we're going to monitor and measure those.

Your description about the services outside of the hospital—I'm also in a private practice, so I have a lot of different diagnosing and imaging facilities in the community. But one control we have is we deal with them under the assumption that they have professionalism and they pass all the quality testing. But when you deal with them on a one-to-one basis after months or years, you somehow know the quality of the report and the testing. You have some control over how you're going to manage that. But in a hospital—actually, in a hospital, you have more control because you have different experts there.

The question is, how do you do this? It's the awareness, learning from the mistake that came about, and then you diligently work toward a goal to make sure that you don't have this happen again, or you mitigate any kind of potential risk.

The Chair (Mr. Ernie Hardeman): Thank you very much. We have another short question from the Liberal side

Ms. Helena Jaczek: Thank you, Chair. Just a very basic question to the CEO, Mr. Musyj: Are you confident in the safety of the drug supply at Windsor Regional Hospital?

Mr. David Musyj: Yes, we are confident. This made us, clearly, take a step back, but we did look at it. At least now it is an isolated—a very isolated—tragic incident that affected a considerable amount of individuals. But as it stands now, yes, I have confidence in not only the system of drugs but also the individuals in the hospital, my team. I have the utmost trust in them.

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Ms. Helena Jaczek: And very quickly: In terms of the 290 patients, what progress are you making—either to you or to Dr. Schneider—in terms of them getting to see their oncologist? Where are we at with that?

Dr. Kenneth Schneider: We've done very well, actually, because we came out fairly quickly with communication to those patients. We've had direct contact with all of them to set up an appointment with their oncologist. A good proportion have already been seen or have attended town halls, and we'll work through the remainder with specific appointments at their request. So we've actually done quite well.

Ms. Helena Jaczek: So what's the outside date?

Mr. David Musyj: Basically, everybody who wanted to see their oncologist has seen their oncologist. Everybody who wanted to wait for their next regularly scheduled appointment is waiting.

Again, that's the insight into the cancer patients. You learn something in health care every day. When they were first contacted by letter and by phone, 50% of them, approximately, said, "I'll wait for my next appointment,

because I know there are individuals who need to see their oncologist sooner rather than later. I'll wait." That's an amazing insight that makes you pause, because of what they're going through personally, that they would reflect and say, "You know what? There are other people in the system who need to see someone sooner."

All 290 patients and families—because unfortunately, 20 have passed since the start of the treatment—have had an opportunity to meet with their oncologist, have either met with them or they're just waiting for their next appointment. Some came to town halls, but I'm very proud of the team who, within a very short period of time, have been able to make direct contact with all 290.

Ms. Helena Jaczek: Thank you very much.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation this afternoon and taking time to come and talk to us. We very much appreciate it. I'm sure it will be of great assistance to the committee as we move forward with this process. So thank you again for coming.

Mr. David Musyj: Thank you, Mr. Chair. Thank you, committee.

MINISTRY OF HEALTH AND LONG-TERM CARE

The Chair (Mr. Ernie Hardeman): Our next delegation is from the Ministry of Health and Long-Term Care: Catherine Brown, assistant deputy minister of health systems accountability and performance. I do believe Catherine was here not too long ago. I believe she was here last week, and I was somewhat going to mention it to her and sympathize with her, because I don't believe many questions were to her in the last panel. In order to be here, she was sworn in, so she doesn't have to do that again today. I just remind her that she is under oath still today.

With that, we thank you very much for coming back. You will have 20 minutes to make your presentation. It's here to be passed out. At the conclusion of the presentation, we will have questions as we had before. We will start with the government side the next time.

I will remind everyone that I didn't realize I had originally started with 20 minutes for each one. But, in fact, if you want to cut it in half, you have every right to do that, and then we will come back to you. I just want to point out, that's more work for the Clerk to have to keep track of the time that's left. We don't have the House clock here to do that. We do appreciate that, but I do want to say that, because people may want to, in fact—rather than splitting it into 20 minutes, you can make the circle and do that next time around for better planning purposes. I apologize to the opposition side. I let them go collectively in the same 20 minutes. But we will stick with the rotation, if you want to leave your time for the second time around.

With that, the presentation or the time is yours now, and we'll turn the floor over to you. Again, thank you very much for being here.

Ms. Catherine Brown: Thank you, Mr. Chair. Good afternoon. My name is Catherine Brown. I'm the assistant deputy minister of the health system accountability and performance division with the Ministry of Health and Long-Term Care. I want to thank you all for being here today.

I'll be telling you today about this ministry's response to the recent situation involving certain cancer drugs in some hospitals, and my role in coordinating that response. I am going to need to set some context about oversight and jurisdiction as I do that. I will also bring you up to speed on important developments over the past few days. After that, I will be pleased to take any questions you may have.

Before I get into that, however, I need to express my sincere concerns for the patients who have been affected by this and for the families who were affected along with them. I am not alone in having spoken these words before this committee, but they cannot be spoken often enough. Something has happened here that should not have, and our job in this room and across the health system is to make sure that it cannot happen again.

My role within the ministry is as follows: I have oversight responsibilities for certain areas of the health care system. For example, I oversee the licensing, inspection and reporting regime enforcing the Long-Term Care Homes Act and its regulations, and the Healing Arts Radiation Protection Act and regulations. This includes setting strategic direction for funding and financial policies for long-term care and other health sectors. I should note that this is the only area of my division where we do actual on-site inspections, where we have inspectors who go out and look at sites, both in radiation and in long-term care.

I also provide oversight in support of the implementation of major new health system strategies and reforms, including the wait times and access-to-care strategy. Our goal is to improve existing programs, with an emphasis on best practices, access to services, and ensuring system accountability.

The division I oversee also works collaboratively with the other divisions in the ministry and in very close partnership with the LHINs, the local health integration networks, to ensure that the obligations of the Local Health System Integration Act and related legislation are met. We work together to improve access to care and health care service delivery while ensuring accountability and performance requirements are met.

With respect to hospitals, Ontario's public hospitals are not-for-profit, community-based corporations. They have their own boards and governance structure. They are subject to a number of pieces of legislation. The sort of key ones, or some of the highest-level ones, are the Public Hospitals Act, the Local Health System Integration Act, which I mentioned earlier, the Broader Public Sector Accountability Act, and the Excellent Care for All Act

Without getting too deeply into the specifics regarding all of those, what that all means is that I, in my role within the ministry, work jointly with our LHINs in providing oversight in support of Ontario's hospitals. My oversight does not include drugs and pharmacies, but I work closely with my colleagues at Ontario Public Drug Programs, which oversees the province's publicly funded drug programs, and with Health Human Resources Strategy division, which oversees the regulatory system for health professionals, which includes the Ontario College of Pharmacists. The college regulates, as you heard last Tuesday, and accredits community pharmacies under the Drug and Pharmacies Regulation Act and regulates the work done by pharmacists and pharmacy technicians in Ontario under the Pharmacy Act.

The final slice of the legislative oversight pie, if you will, is Health Canada, which regulates the manufacture, packaging, labelling and sale of drugs, and also licenses drug manufacturers, all under the federal Food and Drugs Act. This act also provides Health Canada with broad inspection powers in connection with places where drugs are manufactured, prepared, packaged or stored.

That is a snapshot of the oversight structure that was in place in late March, when it was discovered that there was a problem with certain bags of chemotherapy solution in some hospitals. Those bags contained a lower concentration of medication than should have been there—they were diluted—and patients, as a result, had been underdosed.

As you heard last week from Cancer Care Ontario CEO Michael Sherar, the four hospitals in question immediately stopped using those diluted products—and you've heard more on that today from Windsor—and took the necessary steps to ensure they were taken out of circulation and that proper doses were being administered. They then notified CCO, which in turn notified the ministry. I will point out that those steps seem sequential, but everything was pretty much happening all at once, if I can point it out that way.

At the same time, the priority was to identify and contact those patients who had been affected by the use of these products. Notification was done at the hospital level. It is my understanding that all patients or their families have now been contacted, and most have been able to meet with their hospital and oncologists to understand what has taken place. As Mr. Musyj just pointed out, we have also heard from our hospitals that where meetings have not taken place, it's because patients have deferred the meeting to deal with other things, vacations or otherwise; it is not as a result of not having access to someone to meet with.

Upon learning of the situation, Cancer Care Ontario worked with the province's hospitals to ensure that quality assurance processes are in place for all drugs purchased externally or prepared in hospital.

The ministry, meanwhile, struck a working group on April 8 to coordinate the response to this issue. The group, which I am chairing, includes our partners from Health Canada, the Ontario Hospital Association, the Ontario College of Pharmacists, Cancer Care Ontario, the province of New Brunswick, and the four hospitals, along with other ministry representatives.

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We have a full teleconference meeting every day, and we have since April 8. With the exception of day 1, when New Brunswick was not able to participate, we have had full participation on every call. In addition, we hold bilateral meetings whenever they are needed, and that has turned out to be almost every day. We regularly have separate meetings with Health Canada, the hospitals and Cancer Care Ontario as needed, and it's almost daily that we have been having those meetings.

I can say from where I sit that, except for the fact that this incident happened, the system has pulled together and responded with a view to restoring patient care and safety. The four hospitals—London Health Sciences Centre, Windsor Regional, Lakeridge Health and Peterborough Regional Health Centre—moved swiftly and collaboratively to safeguard the care of all their patients. Patients and families were notified. And on April 11, Cancer Care Ontario was able to confirm that all 77 hospitals in Ontario that provide cancer treatment have verified the safety and integrity of their chemotherapy drugs.

With those critical early steps taken care of, the ministry undertook to examine the supply chain that is in place in Ontario and to properly investigate and understand what had happened here, so that we can ensure that it does not happen again.

To that end, as you know, Dr. Jake Thiessen was appointed as an inspector under the provisions of the Public Hospitals Act to lead an independent review to determine how this incident occurred, and provide recommendations to prevent future incidents. He is being supported in this undertaking by the working group.

It is the intention of the Minister of Health and Long-Term Care that Dr. Thiessen's findings will be made public. We are not going to pre-judge them. Until we see Dr. Thiessen's report, we are going to assume that there is much that we don't know.

One thing we do know is that this happened. It boils down to the fact that instead of overlapping, as jurisdictions so often do, the oversight activities of Health Canada federally and the Ontario College of Pharmacists provincially actually fell short of one another. Referring back to the oversight structure I laid out for you earlier, the province, through the Ontario College of Pharmacists, regulates pharmacies and pharmacists—those are the pharmacies within hospitals and in the community. Health Canada has a responsibility for manufacturers. Marchese, the company that mixed and supplied these drugs to the hospitals, fell into a gap between them. They were producing these drugs in a facility that was neither a pharmacy nor licensed as a manufacturer. It was a grey area, and consequently, there was no active oversight.

The province of Ontario is working to eliminate that grey area. On Friday, the province wrote to businesses that it knows of which might possibly be selling compounded drugs to obtain more information about their processes and oversight. As well, on Friday the Minster of Health and Long-Term Care sent a letter to every

hospital in the province asking them to affirm that they have thoroughly reviewed their medication management processes relating to compounding drugs, both onsite and offsite, so that we may assure Ontarians that necessary safeguards are in place. Responses from hospitals are required by April 26. I will note that the letter went out on Friday and that we have heard from a number of hospitals already, that that assurance has been given that their products are safe.

Also on Friday, the government announced that it is proposing a new regulation under the Public Hospitals Act to ensure that hospitals only purchase drugs from accredited, licensed or otherwise approved suppliers. That regulation has been posted for consultation. In addition, we are working with the Ontario College of Pharmacists on a regulation that would give the college the power to inspect any premises where pharmacists and pharmacy technicians are preparing drugs. I know you heard from the college last week that they have been looking hard at the work of pharmacies and pharmacists in this province with an eye to tightening up the system. They have now confirmed that a proposed regulation is in the final stages of development.

Federally, Health Canada has also acted. As you may know, we are convinced that the lead in all of this must be taken by Health Canada, given that this is a problem that has already occurred in more than one province. On Friday, Health Canada responded to that and announced that it is providing direction to organizations involved in the compounding and admixing of medications. Under this direction, companies must either operate inside a hospital, be supervised by a provincially registered pharmacist, or must hold a federal drug manufacturing license.

These are preliminary measures. "Stabilizing solution" is the term that Health Canada used about their framework. For our part, we have taken some measures and look forward to see what Dr. Thiessen concludes and what suggestions he may offer. Until we know these things, we are inclined to view everything being done right now as preliminary but necessary.

Once we have those suggestions, we look forward to continuing to work closely and diligently with Health Canada, Cancer Care Ontario, the College of Pharmacists and our hospitals, as well as with our colleagues in other provinces, to ensure that the supply chain of drugs on which patients in this province and this country depend is as safe as it can possibly be. It is the view of this ministry that no other response to recent events is acceptable. As I have said previously, this cannot happen again.

I will be happy to take your questions.

The Chair (Mr. Ernie Hardeman): Thank you very much for your presentation. With that, we will go to Dr. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Thank you, Ms. Brown. Your presentation is very comprehensive, and I know you were trying to get through it all. I'd like to sort of recap, with perhaps just a little more detail in some areas of what you've had the chance to tell us.

First of all, when did you personally hear of this incident?

Ms. Catherine Brown: I was on vacation, out of the country, the week that this began, and I was notified while I was on vacation. Then I returned to the country on the 6th of April. I was briefed on Sunday, on the 7th, and began working on it first thing on the 8th.

Ms. Helena Jaczek: Right. And you've basically been the lead in terms of looking at responses in terms of what the ministry might be able to put forward to address this grey area.

Ms. Catherine Brown: That is correct.

Ms. Helena Jaczek: As we heard last week—clearly from what we heard, the College of Pharmacists acknowledges that other provinces do have different provisions in terms of their mandate and so on. Could you just zero in on what we're lacking here in Ontario?

Ms. Catherine Brown: The way in which the system is structured in Ontario is that the college has oversight for pharmacists where they practise in community pharmacies, and of course hospital pharmacies are under the jurisdiction of hospitals. Their pharmacists are regulated by the college as well. In Ontario, drug manufacturing, as is the case in the rest of the country, is overseen by Health Canada under the Food and Drugs Act, as I noted.

As the folks from Windsor spoke to, this grey area was not known to us in this way until this happened. How this company is operating outside of that is still not clear to us, and that's why we have these investigations in place.

Ms. Helena Jaczek: You made reference to appointing a third-party expert reviewer. Can you just describe again, in a little more detail, the exact mandate that Dr. Thiessen has?

Ms. Catherine Brown: I can. Dr. Thiessen was appointed under the Public Hospitals Act. He has jurisdiction to go in and look at the four hospitals, and he has jurisdiction to ask anyone else to speak to him about the events that took place here and to look at the procurement chain, if I can say that, and all of the steps along the way, from the contract through to the delivery of chemotherapy, to try and determine where things went wrong

To my understanding, thus far, he has met with the four hospitals and has asked to meet with others and will continue to meet with others who have been part of this, including Health Canada. I believe he's asked for a meeting with Marchese and others.

Ms. Helena Jaczek: Is a possible outcome that he will make a recommendation related to oversight by the College of Pharmacists in Ontario?

Ms. Catherine Brown: He can make whatever recommendation he sees as appropriate to try and determine a better way to do this.

Ms. Helena Jaczek: And, as you've told us, this review will be made public.

Ms. Catherine Brown: Yes.

Ms. Helena Jaczek: Again, the working group—this is the group that you chair: I think you may have alluded

to it, but could you just tell us again who exactly is on that group, why they were chosen?

Ms. Catherine Brown: The group represents everyone that has a piece of this pie, so Health Canada, our partners in oversight; the four hospitals that were involved; the Ontario Hospital Association as it relates to the other hospitals in the system; the College of Pharmacists, of course; my colleagues within the ministry who have related responsibilities, as I noted—drug programs and health human resources. I'm missing somebody. Cancer Care Ontario; I'm sorry. Cancer Care Ontario is a key partner in the delivery of cancer services across this province; 60% of cancer services are delivered by Cancer Care Ontario, so they are part of that group as well.

Ms. Helena Jaczek: Could you describe the relationship, if there is one, between the Ministry of Health and Long-Term Care and Medbuy?

Ms. Catherine Brown: As far as I'm aware, we don't have a direct relationship. Medbuy is a shared service procurement entity. They have contracts that—they offer services to procure on behalf of parties in the health care system, on behalf of hospitals or others. They undertake those activities on their behalf.

Ms. Helena Jaczek: So it really is up to hospitals to make a decision whether they wish to procure product through Medbuy?

Ms. Catherine Brown: That's correct.

Ms. Helena Jaczek: How would you see hospitals to be guided in this procurement practice? We heard reference to Ministry of Finance guidelines and so on. Perhaps from the perspective of the Ministry of Health and Long-Term Care, what would you feel would be appropriate in terms of hospitals safeguarding the safety of the drug supply?

Ms. Catherine Brown: Hospitals are independent corporations. They have their own board of directors, and they have their own accountability and governance for the operations of that entity. They are responsible to ensure that the people with whom they do business are appropriate. Medbuy is one of many shared service procurement organizations through whom people in the health care system procure.

We also provide guidance to the hospitals through the Broader Public Sector Accountability Act, through the broader public sector procurement directive and the rules and guidelines therein about ensuring that there is balance between quality and ensuring that they take the necessary steps to ensure that the products and services that they're procuring are appropriate, and that they are safe and there is quality.

Ms. Helena Jaczek: Mr. Musyj made reference to the quality improvement plan that each hospital much provide, I presume, to the LHIN. Could you just talk a little bit about where that falls into the picture here?

Ms. Catherine Brown: Quality improvement plans are part of the Excellent Care for All Act. These are plans that the hospitals undertake to improve a variety of things under their jurisdiction, including the delivery of service.

Ms. Helena Jaczek: And these quality improvement plans are forwarded to the LHIN or—

Ms. Catherine Brown: They are provided to the LHIN, yes. The LHIN has an agreement with all of its health service providers, and the primary relationship is between the LHIN and the hospital, although the ministry is party to all of those in some way.

Ms. Helena Jaczek: And if the LHIN should be concerned about a particular facility, would the ministry be so informed?

Ms. Catherine Brown: Typically, yes.

Ms. Helena Jaczek: Now, going back to your presentation, you talked about how the government is "proposing a new regulation under the Public Hospitals Act to ensure that hospitals only purchase drugs from accredited, licensed or otherwise approved suppliers." Could you go into more detail and give us some examples of what an accredited, licensed or otherwise approved supplier might look like?

Ms. Catherine Brown: That would include any manufacturer that is licensed under the Food and Drugs Act; any accredited pharmacy under the Ontario Drug and Pharmacies Regulation Act—a corporation that procures products on behalf of a hospital would have to do that in the same way, so it also captures those entities like Medbuy that you just noted; a wholesaler who has bought the drug from a related entity; a specified person inspected by the College of Pharmacists that is not a pharmacy, so an independent pharmacist; another hospital—should they be procuring from another hospital they would need to ensure that those assurances were in place; through another government, both provincially or the Canadian government; an accredited pharmacy in another jurisdiction, as I noted; or a person conducting a clinical trial.

Ms. Helena Jaczek: So essentially, each of those entities you've described from which a hospital could acquire a drug is inspected in some fashion by an entity or Health Canada.

Ms. Catherine Brown: It is regulated in some fashion by one jurisdiction or another, yes—either by Health Canada or by the province in which it resides.

Ms. Helena Jaczek: Again, a little more detail on what Health Canada has proposed—in your presentation, you mentioned that Health Canada "is providing direction to organizations involved in the compounding and admixing of medications." So this would include Marchese itself, Baxter and so on. If you could, again, detail a little bit exactly what that means. What is this direction?

Ms. Catherine Brown: I will say that this is something that Health Canada introduced on Friday and I haven't seen all of the details myself. We understand that their framework would require companies to either operate within a hospital, as many pharmacies do; be supervised by a provincially registered pharmacist, so that would include all of our community pharmacies, for example; or must hold a federal drug manufacturing licence. So they must find themselves within one of those

categories. That is my understanding of the direction. They will be forthcoming with more detail at some point in the near future is my understanding.

Ms. Helena Jaczek: So you feel confident that between the Health Canada announcement on Friday and the proposed regulation that our government has proposed, we would have a safe and secure supply of drugs entering hospitals. Would that be true?

Ms. Catherine Brown: I would believe that those are two steps—two or three; there are several that I've noted—that will take us closer to that. I think until we hear from Dr. Thiessen and what he finds—I would want to be sure that we are responding to what his findings might be, if there is something else that we need to do additionally to ensure that that safety is fully in place.

Ms. Helena Jaczek: I'll save the rest of my time. How much is it, by the way?

The Chair (Mr. Ernie Hardeman): You have about seven minutes left.

Ms. Helena Jaczek: Okay, we'll save that for later.

The Chair (Mr. Ernie Hardeman): The official opposition? Whoever wants to go first.

Mrs. Christine Elliott: I'll start, then. Thank you very much for joining us again, Ms. Brown.

The representatives from Windsor who were just here said that it wasn't really a big problem to change the decision with respect to ordering premixed solutions. This was something that was sort of up to them to decide. I was wondering if you had any guidelines that the ministry issued in this respect or any procedure that needed to be followed in order to make these sorts of decisions within the hospitals.

Ms. Catherine Brown: It is within the hospital's jurisdiction, as you noted, to make those determinations. They are independent corporations. They need to look at how and where they are procuring and ensure that they are doing the best they can to ensure those procurements are safe.

We do not issue particular guidelines around procuring compounded drugs. We issue guidelines around procurements more generally and ensure that those procurements meet a number of criteria. Cancer Care Ontario also issues guidelines around the use of compounded drugs and the labeling of compounded drugs. So there are a number of people or players who have a role in this to provide guidance.

Mrs. Christine Elliott: Is this a trend that's happening, that you're seeing this sort of outsourcing happening? Has it been happening with other drugs through the years or is this something that's just more recent?

Ms. Catherine Brown: No, I think as Windsor pointed out—and I am learning about this over the last many weeks as well—hospitals have been undertaking this work for many, many years, and those hospitals that have a large volume of certain drugs or solutions to be provided have undertaken this for quite some time.

Mrs. Christine Elliott: Are they required to submit reports to you at all or is this something that they just deal with internally within the hospitals?

Ms. Catherine Brown: They submit a variety of reports to us but they don't need to submit reports about every procurement. They need to submit reports ensuring that their procurements comply with the rules of the province, but we don't ask for—to my knowledge, anyway—the particular details of every single procurement. Again, that is up to the hospital. They have a board. They need to assure their board that those procurements are in keeping with the rules of the province, and then they attest to that to the province under the Broader Public Sector Accountability Act.

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Mrs. Christine Elliott: But this would have been something that the ministry would have been aware of, that there were a number of hospitals that were ordering premixed solutions for certain kinds of medications?

Ms. Catherine Brown: The ministry is aware that hospitals procure from other hospitals, third parties, manufacturers. We're aware of that. I'm not sure what knowledge the ministry would or wouldn't have had about this particular procurement.

Mrs. Christine Elliott: Was there ever any discussion, I guess, within your department that you're aware of with respect to this trend, or any discussion, anybody reviewing it, any concerns being issued with respect to it?

Ms. Catherine Brown: There was no discussion that I'm aware of in my division about this, as you describe it, trend. I think this is something that has been going on for many years. I think as Windsor noted in their remarks, this grey area, however it came about—we don't know if this was something where a manufacturer was working around existing rules or if this was just a gap in oversight, but this was not something that had been discussed within my division previously, no.

Mrs. Christine Elliott: All right. Thank you. My colleagues may have some questions.

The Chair (Mr. Ernie Hardeman): We'll make the full circle, so we'll go to Ms. Gélinas.

M^{me} France Gélinas: Jeff, you're not going? I think Jeff wanted to go.

Mr. Jeff Yurek: How many minutes have I got in my time?

The Chair (Mr. Ernie Hardeman): He wasn't here when I explained that we would circle when one was finished, and then the time could be used. But it's fine—

Mr. Jeff Yurek: It's going to be the same question, either way.

The Chair (Mr. Ernie Hardeman): —if we want Mr. Yurek to go first. Mr. Yurek?

M^{me} France Gélinas: Go ahead.

Mr. Jeff Yurek: Thanks, Chair.

Thanks for coming in today. I noticed—and I'll read it out here. It's in your presentation: "The government announced that it is proposing new regulations under the Public Hospitals Act to ensure that hospitals only purchase drugs from accredited, licensed or otherwise approved suppliers."

To me, I would have assumed that would have already been in place. If you went out and polled anybody on the streets, I bet you'd probably think, "Yeah, my hospital does buy from an accredited, licensed or approved supplier." That's common sense. And yet the government didn't have that in place for procurement. Your thoughts on that? I mean, that's a glaring, glaring error.

Ms. Catherine Brown: I think that the province had and the hospitals have very solid procurement rules and they follow them very closely. I think it's unfortunate that we find ourselves having to write a rule like this to ensure that hospitals are looking at those entities and ensuring that they are regulated.

As Windsor pointed out and as has been raised previously with this table, this area of oversight and lack of oversight was not something that any of us understood to exist in this way, and I think that the hospitals themselves were—I can't predetermine what Dr. Thiessen may find, but it is my understanding the hospitals weren't aware that this entity was outside of jurisdiction. I'm not sure how we will find that that happened. So yes, it is unfortunate that we find ourselves having to write such prescriptive rules to remind everyone and to give them the ability to check the credentials of anyone from whom they are purchasing these products.

Mr. Jeff Yurek: So in terms of the hospitals, you treat them as independent businesses, even though it's public health care and you guys are actually in charge of them, the Ministry of Health.

Ms. Catherine Brown: No, I didn't say that. I said that they are independent corporations. They have their own boards, but they are accountable to the province and to the LHINs and to us and to the taxpayer under a variety of pieces of legislation. But they do have their own boards to whom they are also accountable for the operations of those entities, like many, many health care entities across the province.

Mr. Jeff Yurek: So they're accountable to the Ministry of Health and you guys set standards and policies for them to achieve in order to ensure that they're reaching a certain benchmark?

Ms. Catherine Brown: In many areas, yes.

Mr. Jeff Yurek: Except in the procurement of—

Ms. Catherine Brown: No, we have rules on procurement under the Broader Public Sector Accountability Act. There are rules and guidelines on procurement and, as I indicated, they're required to sign an attestation every year indicating that they have operated within those rules.

Mr. Jeff Yurek: So when the hospital has the procurement, and with regards to Medbuy and other third party outsourcing companies that would purchase on their behalf, do you have any policy as to how they enter into an agreement with a company like Medbuy or any other ones out there, or is that left up to their devices?

Ms. Catherine Brown: The policies around procuring from a second party or a third party would be the same policies around how they procure. They are required to procure in the same way, ensuring quality and all of those other aspects around a procurement.

Mr. Jeff Yurek: Okay. I'm good.

The Chair (Mr. Ernie Hardeman): Okay. France Gélinas.

M^{me} France Gélinas: We just had a number of representatives from the Windsor hospital come and talk to us, and it became clear from their opening remarks and from the answers to our questions that as players in the hospital and in the cancer system, they interact with an awful lot of partners. They take it for granted that all of those partners that are part of our health care system are regulated, that they have oversight, that they can be trusted to be regulated, to have oversight. Basically, this is how they can do their work, because they're never going to do it all. There's always a part that is done elsewhere, whether a lab test or an X-ray, a cardiogram or whatever, but they trust that either the independent health facilities or the multiple areas that make up our health care system have oversight.

You head the health system accountability and performance division. How long have you been the ADM for that division?

Ms. Catherine Brown: Since September of last year. **M**^{me} **France Gélinas:** Okay, and how long has this division been there?

Ms. Catherine Brown: I'm going to say seven years, eight years.

M^{ne} France Gélinas: Okay. So, basically, when the Ministry of Health changed its focus to be more of a steward, it put this new health system accountability and performance division in place to do the oversight of their health care system, and you happen to be the ADM of this. The questions that are at the core of this are: How could it be that a part as important as procuring drugs was operating without any oversight? How could it be that we had that grey area and that after seven years of having an ADM—not you but people before you—of health system accountability, nobody had noticed that there was a grey area?

Ms. Catherine Brown: I will just comment: It was not operating without oversight. We understood in Ontario that the areas that produced pharmaceutical products, such as manufacturers, were fully under the jurisdiction of Health Canada. Health Canada believed that their manufacturing oversight was intact.

We further believe that in Ontario's jurisdiction we had fully covered off pharmacies in the community and in hospitals and had full jurisdiction over pharmacists in the province. That this area exists is something that, as you point out, was not known to us, and how it came to be, we're still unclear on. Whether any of these entities are operating completely outside of oversight—it would appear this one was. How they came to be doing this is unclear to us.

As I mentioned in my remarks, we have asked those entities that we know that do similar work to this to provide for us information about how they are operating. Health Canada is aware that we have undertaken to send those letters. At the same time, Health Canada is asking those entities that are providing compounded solutions to let them know that they're operating under provincial

jurisdiction or federal jurisdiction, so that we can shine a light on those who are operating between the rules, if I can say it that way. How they came to be between the rules may be something they have chosen to do, or it may in fact be a gap that arose in a way that none of us anticipated.

M^{me} France Gélinas: We've all now been following the series of documents that have been put forward by Health Canada. Since 1997, they have talked—and I would say even warned—of a grey area of oversight, specifically between the manufacturing and the compounding of drugs. Those have been shared with the provincial government. I didn't see the one that's dated 1997, but we saw 2001 on. For the last 12 years, we know that there's a grey area of oversight, and nobody does anything. How come?

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Ms. Catherine Brown: It is my understanding that Health Canada has been looking at this issue for some time. The provinces have responded to Health Canada in that regard. It is very clear what the province's jurisdiction is in this in regard to pharmacies and pharmacists. This is not a pharmacy. It's not a pharmacy by the rules of any province. It is some form of manufacturing. And as you pointed out, I believe, last week, looking at the federal policy, it identifies that where it falls outside of provincial jurisdiction, it is within federal jurisdiction.

M^{me} France Gélinas: And vice versa. So here we are for 12 years, maybe longer—we could even say for 15 years, since it was identified in 1997. We know that there's a grey area, but yet no action. Then, from the time you come back on April 7 to last Friday—so in 10 days—we are able to put oversight, change directives to the hospital and basically be very proactive on a file. Within 10 days, we were able to do all of this, yet within 15 years we did nothing. I'm having a really tough time with that. It seems that the steps that you have put forward were not very difficult. You could have taken them, frankly, years ago.

Ms. Catherine Brown: The rules that the province has put in place, as Mr. Yurek pointed out, are to prevent hospitals from procuring from an entity that is in the grey zone. Health Canada has stepped up to issue a directive to require entities like this, under their federal law—the province has taken every step it can under the jurisdiction it currently has to oversee pharmacists and pharmacies in Ontario. As I mentioned previously, this is not a pharmacy. It is a type of manufacturer, and Health Canada has moved forward in the last week to undertake this direction that it has provided on Friday.

We have indeed taken a number of steps over the last two weeks in response to what we can do within Ontario to prevent this from happening again.

M^{me} France Gélinas: All right. So we know for a number of years that there's a grey area. We also know that all that the government of Ontario, the Ministry of Health, has to do is issue—what have you called it?—a proposed new regulation that hospitals only purchase drugs from accredited, licensed or otherwise approved

suppliers. Had we done this when the grey area was identified, I think that there's a lot of hardship that would have been avoided. Do you agree?

Ms. Catherine Brown: I can't comment on what hypothetically might have happened if we had done this. As I mentioned and as I mentioned in response to Mr. Yurek's question, I think it is very unfortunate that we find ourselves here. As Windsor pointed out, none of us anticipated that anybody would be trying to work around the rules. We did what we needed to do when this situation arose. We took every step possible within our jurisdiction to respond to this and to ensure patients were safe and to ensure that this is prevented going forward, and we will continue to do that when we hear from Dr. Thiessen what has caused this incident to arise.

M^{me} France Gélinas: But isn't it your job to think forward that things like this could happen? We know there's a grey area. You hadn't anticipated that they would do something like this, but the precautionary principle—how much harm would there have been to say, "We've identified a grey area. Just to make sure that nothing derails, we will make sure that when you procure drugs and you have this fancy little language here, you only purchase drugs from accredited, licensed or approved suppliers"?

It worries me that if you haven't been any more proactive in this, what happens to other programs and services that used to be in hospitals that are now being more and more provided in the community? Isn't it your job to be proactive?

Ms. Catherine Brown: It is our job to do our best to be as proactive as possible, and yes, there are things that we do every single day to try and look forward and look around those corners to anticipate this type of thing. As Windsor pointed out, it has shone a light on this kind of area. We are looking to be sure that there isn't anything else like this that we hadn't anticipated that may cause a problem. We are doing everything that we can within our jurisdiction to try and ensure that this doesn't happen again.

I will say that we don't know that the—the lack of oversight is a lack of oversight. We still don't know what caused this problem. We don't know that the lack of oversight is what caused this problem in the system. Dr. Thiessen's work is looking all of the steps in the procurement, in the way in which the procurement was worded and the way in which the instructions to prepare the products were undertaken. It may be that it was as a result of the oversight; it may be that it was not. Regardless, we are taking steps to ensure that we change the way in which those procurements are undertaken and ensure that companies that operate outside of the rules are not part of the procurement chain in Ontario.

M^{me*}France Gélinas: There are many other parts of our health care system—as hospitals divest themselves and concentrate on their core mandate of providing acute hospital care, every other program and service that used to be done in the hospital, more and more are being done in the community and more and more are being done by

unregulated—is this an alarm bell for you that you will get really active in your role at health systems accountability to make sure that we build regulations for all of this community side that is unregulated?

Ms. Catherine Brown: I'm not sure of the pieces of the system that you're referring to that are unregulated. As part of my role, we look at ensuring that the professionals that provide health services to people across Ontario are regulated, that they are abiding by rules that are set out by their professional associations or otherwise, that we ensure that there is oversight, that where we have inspection capacity, we utilize that, or, where a college is regulating those professions, that they are ensuring that those professionals are undertaking their responsibilities in accordance with their rules.

M^{me} France Gélinas: They do, and they do that well. Once a regulation process is in place, I think it has served us well, but the question remains: How come you don't know what part of the system is not regulated? Shouldn't you know that? Would you like me to rhyme some off for you?

Ms. Catherine Brown: No, I didn't say I don't know what part of the system is unregulated. I said I wasn't sure what part of the system you were referring to that was unregulated.

M^{me} France Gélinas: Okay. So my question then: Do you know what other parts of the system are not regulated?

Ms. Catherine Brown: We work very closely with all of our health service providers, all of the entities that we fund through the LHINs or directly, to ensure that they have guidance over the services they are provided, either through their respective regulatory bodies or otherwise, to ensure that there is accountability in the system for all health service providers at every level.

M^{me} France Gélinas: But you know that there are services out there that are unregulated?

Ms. Catherine Brown: I'm trying to think what service you would be referring to. Perhaps you could tell me what one you're referring to.

M^{me} **France Gélinas:** Let's start with palliative care homes. What kind of regulation does the ministry have over palliative care homes?

Ms. Catherine Brown: The professionals that operate within a palliative care home would be guided by the rules of their profession, and—

M^{me} **France Gélinas:** But the home as a whole?

Ms. Catherine Brown: Palliative care residences are funded by the LHINs, and we look at the care plans that they provide and the services that they provide. They are part of the health care system. They have health service providers within their four walls who are regulated, and they have other service providers, like cleaners and cooks who are not necessarily regulated health professionals.

M^{me} France Gélinas: I could tell you more. Like, patient transport is supposed to have regulations for interfacility patient transport. They're still unregulated. They're still operating out there. I'm not interested in

going there. I'm more interested in—I'm disappointed that after what has just happened, there is great interest in one particular area, the supply chain of chemo drugs because that particular area derails because there was no oversight, because it was not regulated. But then it doesn't seem to have sparked any kind of a willingness to look at other parts of the health care system that are in exactly the same situation as what we had. They may not be supplying chemo drugs to our cancer patients, but they are still in the same situation as what brought us here.

I sort of thought that with a title such as health system accountability and performance division, you would keep an eye on those things and say, "Well, here's a call to arms, to really go forward and regulate part of the health system," especially as, as more and more hospitals divest themselves of programs and services going into the community, oversight of the divestment is not happening. You are in charge of this. Why isn't it happening?

Ms. Catherine Brown: It is not to say it is not happening. Respectfully, we have spent the last several weeks focused very hard on this issue to ensure that we are taking every step possible, that the hospitals are taking every step possible, that we are ensuring that our partners at Health Canada are doing their part to address this issue that is before us. We look across the rest of the health care system on a regular basis, and continue to do so, to ensure that appropriate accountabilities are in place for all types of service provision. To say that we have not done that over the last several weeks is somewhat incorrect. We continue to look always for where we can apply greater accountability across the system. My focus, and the focus of key people on my team, in the last three weeks has been on this issue and making sure that we are doing everything we can to support the hospitals, the patients who were impacted, and making sure that we bring this problem to ground very quickly and put the rules in place that are necessary to prevent it from happening again. It's not to say we're not continuing to look elsewhere across the health care system for where there needs to be greater oversight or accountability. We do that regularly.

M^{me} France Gélinas: So if we find other areas where the federal government identified grey accountability areas, where their oversight ends and yours starts and there is no overlap, are you presently reviewing where those exist?

Ms. Catherine Brown: We are looking at all areas of the—we regularly look at all areas of health care as we go forward.

And to your point that Health Canada identified this issue, Health Canada has been looking at this issue for a number of years to determine where they could take greater action in this area. The provinces have been responding to Health Canada as they are asked to do that, and Health Canada has, as of Friday, taken a step forward in addressing this issue.

M^{me} France Gélinas: I'll save my time.

The Chair (Mr. Ernie Hardeman): Okay. Thank you. Ms. Jaczek.

Ms. Helena Jaczek: Thank you, Chair. Ms. Brown, I just want to go through a little bit of your role vis-à-vis the role of your colleagues in the Ontario public drug programs, which oversees the province's publicly funded drug programs, and the health human resource strategy division, which oversees the regulatory system for health professionals. I have my Ministry of Health and Long-Term Care org chart here. I look at it regularly because it's a little confusing. These are two other ADMs.

Ms. Catherine Brown: Yes.

Ms. Helena Jaczek: These are your colleagues and perhaps have more direct oversight. But presumably you could help us a little bit with the College of Pharmacists. Are you aware of, or have any of your colleagues ever brought to your attention, what we heard last week from the relatively new registrar of the Ontario College of Pharmacists, that there was a grey area in terms of lack of oversight by the college in this area? Were you made aware of this?

Ms. Catherine Brown: I was not made aware of this until this, but I am, as I said, relatively new to this portfolio and the area around drug programs is the responsibility of a colleague. The college is an oversight body.

The regulators: To your point, actually, and I should have made this clear earlier, it is the regulators who typically deal with Health Canada most directly on these issues, to your point on having Health Canada having identified it some time ago. The regulators would tell you that they also had identified it to Health Canada some time ago as being outside their jurisdiction for pharmacies and pharmacists, and raising with Health Canada the need for Health Canada to address this issue. I couldn't comment on when the regulator here in Ontario may have or not brought that issue to the attention of anyone in the ministry. I don't know.

Ms. Helena Jaczek: Right, but obviously well aware of it. This regulation that we have proposed will allow the College of Pharmacists to enter into the premise of this particular compounding facility and others like it?

Ms. Catherine Brown: That is our understanding of what the college will be recommending—it is the college that would recommend the regulation—that they would like jurisdiction to be able to go into these types of premises. But they would still have jurisdiction only for—if I can use the word—"sanctioning" those actions of the pharmacists within that entity. They still would not have jurisdiction to shut down that kind of entity because they only have that role over pharmacies or pharmacists, and this is more a manufacturer of sorts, someone who's preparing products and distributing them rather than a pharmacy.

Ms. Helena Jaczek: In other words, if they went into a compounding facility and they found some sort of error, they would be able to have some sort of sanction against the pharmacist, that individual.

Ms. Catherine Brown: Correct, pharmacists or pharmacy technicians. Those are the categories of professionals they oversee.

Ms. Helena Jaczek: In terms of your role, health system accountability and performance, how have you

felt—you're having these daily meetings with the working groups in the hospitals and so on—in terms of the quality assurance measures that hospitals—we heard from Windsor Regional—have in place to ensure the safety of the drug supply within the hospital? What is your analysis of their quality assurance programs?

Ms. Catherine Brown: They have good quality assurance programs in place, both for products that are prepared within their hospitals and also for those that they procure from someone else. I think, as Windsor noted, it was surprising to them that someone from whom they were procuring—that an error had been made, if in fact they had made an error, and that they were outside of a regulated authority.

Ms. Helena Jaczek: Right. Now again, your working group is meeting regularly. Is one of the questions that you've been considering, what other companies are out there like Marchese?

Ms. Catherine Brown: We have talked about that, and talked about that with Dr. Thiessen. As I noted, letters were sent on Friday to entities we know of that might be preparing compounded products for purchase by hospitals or a third party, to ask them under what regulatory authority they are operating, to get a better understanding of that.

Ms. Helena Jaczek: Have you contacted Medbuy at all? They've had requests for proposals and so on. They must have a list of names of companies.

Ms. Catherine Brown: It is one of the vehicles that we use to identify those companies, not necessarily through Medbuy, but to look at the kind of entities that companies like Medbuy—there are many of them—are procuring this type of product from. That is one of the ways we identified the companies that we have gone to.

Ms. Helena Jaczek: Do I have any time left?

The Chair (Mr. Ernie Hardeman): You have about three minutes left.

Ms. Helena Jaczek: I'll save it, just in case.

The Chair (Mr. Ernie Hardeman): The official opposition, Mr. Yurek.

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Mr. Jeff Yurek: Just going back to my question about—you talk about extending the Ontario College of Pharmacists' ability to go in and inspect the premises and not shut down the facility. That's still going to leave a grey area at the end of the day. Just going into my other critic field that I'm in, in auto insurance you see health clinics running that are using health care professionals without them knowing that there's fraudulent activity going on. If there's no deterrent in the system to shut down a manufacturing facility that is not doing the correct things, even though the pharmacists are on duty, or the pharmacy technicians, that's not really going to stop someone who is unscrupulous in the system from using pharmacists or pharmacy technicians to get to their end result. So—

Ms. Catherine Brown: I'm not sure what the question is.

Mr. Jeff Yurek: The question is, therefore, do you think that's enough? I'm seeing a gaping hole right there that's still going to create a grey area. Do you have any thoughts on that?

Ms. Catherine Brown: The rules that—we haven't seen what the college is going to propose in the way of its new regulations or what it would like to see. In my understanding of how I described it, it would still allow Health Canada to go in and say—if we were to say we don't want the pharmacists practising there, or the college was to say that, Health Canada still has authority to go in and shut them down as not being under their regulatory authority, as a manufacturer. So in my understanding that doesn't leave a gap. Health Canada can fill that gap.

Mr. Jeff Yurek: Okay. And have you reviewed what other provinces are doing with regards to procuring medication outside of hospitals?

Ms. Catherine Brown: We have looked at other provinces in this regard, and lots of provinces procure products from outside the hospital. Chemotherapy drugs some provinces procure outside their hospital, less so than Ontario just because of volume, but some of the larger provinces—Alberta, BC—procure from a third party or a second party outside, yes. In fact, as you know, New Brunswick was one of the provinces that procured from Marchese under this contract.

Mr. Jeff Yurek: Procured in Ontario from the company—

Ms. Catherine Brown: They procured the products from Marchese in Ontario, yes, but for use in New Brunswick. So lots of provinces and lots of hospitals undertake this activity on a regular basis.

Mr. Jeff Yurek: Now, do they have oversight or standards at the provincial level overseeing the hospitals?

Ms. Catherine Brown: From the work that we have done over the last number of weeks, it would appear that this particular issue is an issue for all provinces and all provinces were of the same—many provinces; I can't speak for all of them. Many provinces certainly from the conversations that we have had with them were of the same view, that this was under the jurisdiction of the federal government and they were not aware that it was not being, if I can say, covered off.

Mr. Jeff Yurek: Okay. Jane, do you have a question? We'll hold our minutes.

The Chair (Mr. Ernie Hardeman): Thank you very much. Ms. Gélinas.

M^{me} France Gélinas: You have explained to us that Dr. Thiessen is looking and will do a report that will be made public, and he is free to talk to whomever he wants. How are you making sure that whoever wants to talk to him is free to do so?

Ms. Catherine Brown: I'm not sure I understand the question.

M^{me} France Gélinas: I'm looking at whistle-blower protection. I'm looking at people who work within the system who have a story to tell but don't feel that they could come forward without risking their job.

Ms. Catherine Brown: We have certainly made known that anyone can come forward and ask to meet with Dr. Thiessen. We are working with the key people just to set up those appointments. Nothing thus far has come to our attention or to his in that regard—not that I'm aware of. I haven't talked to Dr. Thiessen since late last week, but I'm not aware that he's heard from anyone.

M^{me} **France Gélinas:** Okay. Are you aware if he reaches out to some of the pharmacy technicians and some of the people who work in the field—

Ms. Catherine Brown: I'm not a party to the discussions that he is having. I know that when he goes to the hospitals, he asks to meet with anyone and everyone who would like to meet with him. I know he has those meetings—has had a number of discussions in the hospitals, but we are not part of those discussions, as it's an independent review.

M^{me} **France Gélinas:** If you were made aware that there are people who feel threatened, who feel their job would be in jeopardy, if they were to speak and say what they have to say, what kind of assurance can the government and can you offer those people?

Ms. Catherine Brown: We would certainly put them in touch with Dr. Thiessen and allow that conversation to happen. I guess it would depend on where the individuals resided in their organization. Certainly, most labour relations laws allow for that kind of protection, whistle-blowing protection, and protection from reprisal. We would try and offer that same assurance to anyone outside of a union.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes all the time.

The Liberal side?

Ms. Helena Jaczek: Thank you, Chair. As we've said in this committee last week and again, this is an opportunity to learn and to ensure that there aren't any other grey zones. I guess, picking up a little bit on my colleague Ms. Gélinas: As chairing this working group, you've outlined some of the areas you've been looking at. Has it triggered any thoughts of further investigation, not perhaps related directly to this incident but looking more systemically, in your capacity as ADM for health accountability?

Ms. Catherine Brown: We're certainly looking at—absolutely. As I think it was Dr. Ing from Windsor stated, when these things happen, they are terribly unfortunate and difficult for the patients who are impacted. As public servants, it calls upon us to do whatever we can but also to look as hard as we possibly can at other areas within our jurisdiction to be sure that there isn't something else like this. As we've had these discussions, as was mentioned by Mr. Yurek and others, about: What is in the procurement rules? Does there need to be more? Is there anything we should be doing in addition to the work that we've already spoken about today? We continue to look not just at this area but other areas of oversight and accountability with this light on them, if I can say it that way.

Ms. Helena Jaczek: And then, as we've said again, the care of the patients is absolutely paramount—those who have been affected. You're in daily discussion with the hospitals. How are you feeling about the progress being made in that regard?

Ms. Catherine Brown: I think that the hospitals have done an extraordinary job in their work, reaching out to the patients and their families. I know that they have left no stone unturned in ensuring that they reach every single person that has been impacted. We have heard of the extraordinary things that they have done—the very difficult conversations that the oncologists and the hospitals have had; the extraordinary conversations, as was mentioned by Mr. Musyj, where patients have said, "Talk to someone who's in greater need than me. I'm fine for now."

It has been extraordinary what the hospitals have done in such a short time, as is necessary in this circumstance, and they've really risen to this challenge.

Ms. Helena Jaczek: Thank you.

The Chair (Mr. Ernie Hardeman): Thank you very much. That concludes everyone's time.

We thank you very much for coming in this afternoon to help us out with this information meeting. Thank you very much. A couple of items: As you can tell, there's a bit of a challenge with the timing of the delegations each day, with the time each delegation gets. Between now and the end of the time allotted, there isn't time for another delegation. We'll find the same thing tomorrow when the two hours—you can get two delegates in in two hours. So I would ask the subcommittee if we wanted to meet slightly after—actually, today it would work, but tomorrow it won't. If we'd ask the subcommittee to just stay for an unofficial meeting so we can make a decision of how we deal—either changing the time a little bit for each delegation, or have this time left over—so if the subcommittee would meet after this one.

I also wanted to point out that on your tables are the reports that were asked for in the last meeting. They've all been provided here.

Interjection.

The Chair (Mr. Ernie Hardeman): From Cancer Care Ontario. If they are not sufficient to what you requested, make sure you let us know so we can go after them further.

With that, thank you again. We'll hopefully have a quick meeting with the subcommittee. This meeting stands adjourned.

The committee adjourned at 1630.

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